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मानक

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Mazdoor Kisan Shakti Sangathan

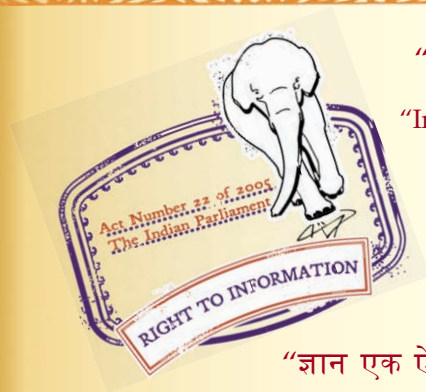
“The Right to Information, The Right to Live”

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Jawaharlal Nehru

“Step Out From the Old to the New”

IS 5551 (1970): Warfarin-sodium, Technical [FAD 1:  
Pesticides and Pesticides Residue Analysis]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”



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IS:5551-1970

*Indian Standard*  
SPECIFICATION FOR  
WARFARIN-SODIUM, TECHNICAL

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August 1970

# Indian Standard

## SPECIFICATION FOR WARFARIN-SODIUM, TECHNICAL

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# Indian Standard

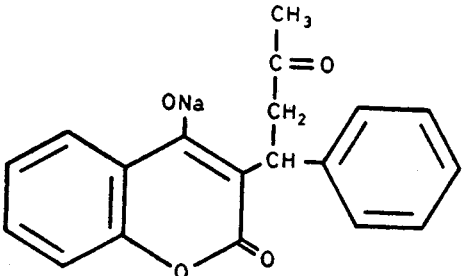
## SPECIFICATION FOR WARFARIN-SODIUM, TECHNICAL

### 0. FOREWORD

**0.1** This Indian Standard was adopted by the Indian Standards Institution on 27 February 1970, after the draft finalized by the Pest Control Sectional Committee had been approved by the Agricultural and Food Products Division Council and the Chemical Division Council.

**0.2** The sodium, salt of 3-acetonylbenzyl-4-hydroxycoumarin, namely, 'Warfarin-Sodium' is used in the preparation of formulations for the control of rodent pests, such as rats, mice and bandicoots. The material acts as an hæmorrhagic agent or as an anti-coagulant, which when eaten for a period of time, causes death due to hæmorrhage in the blood system.

**0.2.1** The structural and chemical formulæ and the molecular weight of the compound are given below :

<i>Empirical Formula</i>	<i>Structural Formula</i>	<i>Molecular Weight</i>
$C_{19}H_{15}O_4Na$		330.0

**0.3** Warfarin-sodium, technical is known to have two impurities, namely, Alice's ketone [3-(o-hydroxyphenyl)-5-phenyl-2-cyclohexene-1-one] and benzalacetone, alkali insolubles. These impurities, when present beyond a certain limit, tend to repel the rats from accepting the bait containing this product. The limits for these impurities have been established in some overseas standards and some investigations have also been

carried out in the country by feeding Indian rats with warfarin containing variable quantities of Alice's ketone only. On the basis of the results of the existing investigations, this standard prescribes the maximum limit of Alice's ketone as 750 ppm in warfarin-sodium, technical. This limit may have to be amended after the investigations, that are still in progress, have been completed. The limit for benzalacetone, alkali insolubles may also have to be specified after the investigations are over.

**0.4** Taking into consideration the views of producers, consumers, testing authorities and technologists, the Sectional Committee responsible for the preparation of this standard felt that it should be related to the manufacturing and trade practices followed in the country in this field.

**0.5** This standard is one of a series of Indian Standards on pesticides and their formulations.

**0.6** This standard contains clauses **3.1**, **F-2.3** and **F-3.4** which call for agreement between the purchaser and the vendor.

**0.7** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS:2-1960\*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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## **1. SCOPE**

**1.1** This standard prescribes the requirements and the methods of test for warfarin-sodium (sodium salt of 3-acetylbenzyl-4-hydroxycoumarin), technical.

## **2. REQUIREMENTS**

**2.1 Description**—The material shall be in the form of a free-flowing, yellow to brownish, crystalline powder, free from any lumps, extraneous impurities, added modifying agents or odours which may limit its suitability for baiting rodents or impair its effectiveness.

**2.2** The material shall comply with the requirements specified in Table 1.

## **3. PACKING AND MARKING**

**3.1 Packing**—The material shall be packed in clean and dry air-tight containers made of galvanized steel sheet, tinplate, steel, glass or plastic as agreed to between the purchaser and the manufacturer.

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\*Rules for rounding off numerical values (*revised*).

**TABLE 1 REQUIREMENTS FOR WARFARIN-SODIUM, TECHNICAL**  
( Clause 2.2 )

Sl No.	CHARACTERISTIC	REQUIREMENTS	METHOD OF TEST ( REF TO APPENDIX )
(1)	(2)	(3)	(4)
i)	Sodium salt of 3-acetonylbenzyl-4-hydroxycoumarin, percent by weight, <i>Min</i>	92.0	A
ii)	Sieving requirement, material passing through 151-micron IS Sieve*, percent by weight, <i>Min</i>	95.0	B
iii)	Moisture content, percent by weight, <i>Max</i>	1.0	C
iv)	Material insoluble in distilled water at 30°C, percent by weight, <i>Max</i>	0.2	D
v)	Alice's ketone, ppm, <i>Max</i>	750	E

\*See IS : 460-1962 Specification for test sieve ( *revised* ). The apertures of BS Sieve 100, ASTM Sieve 100 and Tyler and Sieve 100 are within the limits specified for the above IS Sieve and may, therefore, be used in place of the IS Sieve.

**3.2 Marking**—The containers shall be securely closed and sealed airtight after filling them with the material and shall bear legibly and indelibly the following information:

- Common name of the material;
- Name of the manufacturer;
- Date of manufacture;
- Batch number;
- Net weight of the contents;
- Active ingredient content, percent by weight; and
- The minimum cautionary notice worded as under:

**'DANGEROUSLY HAZARDOUS. KEEP THE MATERIAL AND BAITS CONTAINING THE MATERIAL AWAY FROM CHILDREN, DOMESTIC ANIMALS, FOODSTUFFS, AND ANIMAL FEEDS. DO NOT USE THE EMPTY CONTAINER FOR STORAGE OF FOODSTUFFS OR FEEDS. ANTIDOTE: MASSIVE DOSES OF VITAMIN K, AND IF FOUND NECESSARY, BLOOD MAY BE TRANSFUSED.'**

**3.2.1** In addition to the above, the container shall be marked with the symbol for danger of poisoning as specified in IS: 1260-1958\*. The word 'POISON' in distinct bold capital letters shall be printed.

**3.2.1.1** The containers may also be marked with the ISI Certification Mark.

**NOTE** — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

## **4. SAMPLING**

**4.1** Representative samples of the material shall be drawn as prescribed in Appendix F.

## **5. TESTS**

**5.1** Tests shall be carried out as prescribed in the appropriate appendices specified in col 4 of Table 1.

**5.2 Quality of Reagents** — Unless specified otherwise, pure chemicals and distilled water (see IS: 1070-1960†) shall be employed in the tests.

**NOTE** — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

# **A P P E N D I X A**

[Table 1, Item (i)]

## **DETERMINATION OF SODIUM SALT OF 3-ACETONYL-BENZYL-4-HYDROXYCOUMARIN**

### **A-1. APPARATUS**

**A-1.1 Spectrophotometer** — ultra-violet, with 1-cm quartz cells.

\*Code of symbols for labelling dangerous goods.

†Specification for water, distilled quality (*revised*).

**A-2. REAGENT****A-2.1 Standard Sodium Hydroxide Solution — 0.1 N.****A-3. PROCEDURE**

**A-3.1** Weigh accurately about 50 mg of the sample, transfer the same to a 100-ml volumetric flask, add standard sodium hydroxide solution to effect solution, and make up to the mark with the same. Dilute 2 ml of this solution to 100 ml with the standard sodium hydroxide solution. Set the spectrophotometer at maximum sensitivity and determine the absorption of the final solution at 308 nm using standard sodium hydroxide solution as reference.

**A-4. CALCULATION**

**A-4.1** Molecular weight of sodium salt of warfarin = 330.3

Molar extinction coefficient (*see* Note) =  $1.42 \times 10^4$

Sodium salt of 3-acetonyl-  
benzyl-4-hydroxycoumarin  
content, percent by weight = 
$$\frac{E \times 330.3 \times 100 \times 100 \times 100}{1.42 \times 10\,000 \times 2 \times W} = \frac{E \times 11.6}{10}$$

where :

$E$  = absorption of the final solution at 308 nm, and

$W$  = weight of sample (g).

NOTE—The molar extinction coefficient should be determined with pure sodium salt of 3-acetonylbenzyl-4-hydroxycoumarin. The value given here is an example only.

**A P P E N D I X B**

[ *Table 1, Item (ii)* ]

**TEST FOR SIEVING REQUIREMENT****B-1. APPARATUS**

**B-1.1 Test Sieve**—151-micron IS Sieve (*see* IS:460-1962\*), prepared for test by removing any film, grease or other water-repellent material and then drying.

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\*Specification for test sieves (*revised*).

**B-1.2 Weighing Dish** — tared, one.

## **B-2. METHOD**

**B-2.1** Weigh accurately 100 g of the material and transfer it to the test sieve. Cover the sieve and screen the material in a suitable sieve vibrator for 10 minutes. Two small square rubber cubes are introduced along with the material on the sieve to facilitate the breaking up of any soft lumps of the caked material. After 10 minutes stop the machine and brush the residue on the sieve into a tared weighing dish. Weigh the dish and determine the weight of the residue.

## **B-3. CALCULATION**

**B-3.1** Material passing through 151-micron  
IS Sieve, percent by weight  $= 100 \frac{(1-w)}{W}$

where

$w$  = weight in g of the material retained on the test sieve, and

$W$  = weight in g of the material taken for the test.

# **A P P E N D I X C**

[ *Table 1, Item (iii)* ]

## **DETERMINATION OF MOISTURE CONTENT**

### **C-1. PROCEDURE**

**C-1.1** Weigh accurately 2 g of the sample into a dry tared dish of nickel, platinum or aluminium. Keep the dish in an air-oven maintained at  $101^{\circ} \pm 1^{\circ}\text{C}$  for 10 hours. Afterwards, cool in a desiccator and weigh. Dry the material again for one hour. Cool and repeat this process until the change in weight is not greater than 2 mg. Report the loss in weight as moisture content (*see C-2*).

### **C-2. CALCULATION**

**C-2.1** Moisture content, percent by weight  $= \frac{100 (W - w)}{W}$

where

$W$  = weight in g of the material taken for the test, and

$w$  = weight in g of the material after drying.

## APPENDIX D

[ Table 1, Item (iv) ]

### DETERMINATION OF MATERIAL INSOLUBLE IN DISTILLED WATER

#### D-1. PROCEDURE

**D-1.1** Weigh accurately 5 g of the sample into a 250-ml beaker, add 50 ml of distilled water and heat it to 30°C while stirring until all the soluble material is dissolved. Filter the solution through a dry tared Gooch or sintered glass crucible of porosity No. 3 and wash with 100-ml portions of distilled water at approximately 30°C. Dry to a constant weight in an oven at 110°C. Cool and weigh.

#### D-2. CALCULATION

**D-2.1** Material insoluble in distilled water  
at 30°C, percent by weight  $= \frac{100 \times w}{W}$

where

$w$  = weight in g of the residue after drying, and

$W$  = weight in g of the material taken for the test.

## APPENDIX E

[ Table 1, Item (v) ]

### DETERMINATION OF ALICE'S KETONE IN WARFARIN-SODIUM, TECHNICAL

#### E-1. PROCEDURE

**E-1.1** Dissolve 1.17 g of sample of warfarin-sodium, technical in 10 ml of 5 percent aqueous sodium hydroxide solution. Determine the optical density in a Beckman DU spectrophotometer (or similar instrument) at 385 nm through a 1-cm light path. The parts per million of 'Alice's ketone' is  $380 \times$  optical density.

## APPENDIX F

( Clause 4.1 )

### SAMPLING OF WARFARIN-SODIUM, TECHNICAL

#### F-1. GENERAL REQUIREMENTS

**F-1.0** In drawing, preparing, storing and handling test samples the following precautions and directions shall be observed.

**F-1.1** Samples shall not be taken in an exposed place.

**F-1.2** The sampling instrument shall be clean and dry when used.

**F-1.3** Proper precautions shall be taken while drawing samples since the material is toxic.

**F-1.4** Precautions shall be taken to protect the samples, the material being sampled, the sampling instruments and the receptacles for samples from adventitious contamination.

**F-1.5** To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by shaking or by any other suitable means so as to bring all portions into uniform distribution.

**F-1.6** The samples shall be placed in suitable, clean, dry and air-tight sample receptacles.

**F-1.7** The sample receptacles shall be of such a size that they are almost, but not completely, filled by the sample.

**F-1.8** Each sample receptacle shall be sealed air-tight after filling and marked with full details of sampling, the date of manufacture, name of the manufacturer and other particulars of the consignment.

**F-1.9** Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

#### F-2. SCALE OF SAMPLING

**F-2.1 Lot**— All the containers in a single consignment of the material drawn from the same batch of manufacture shall constitute a lot. If a consignment is declared or is known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

**F-2.1.1** Samples shall be tested for each lot for ascertaining the conformity of the material to the requirements of the specification.

**F-2.2** The number ( $n$ ) of containers to be chosen from the lot shall depend on the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

**F-2.3** These containers shall be chosen at random from the lot and in order to ensure the randomness of selection, some random number table as agreed to between the purchaser and the vendor shall be used. In case such a table is not available, the following procedure shall be adopted:

Starting from any container in the lot, count them as 1, 2, 3, etc, up to  $r$  in a systematic manner, where  $r$  is equal to the integral part of the value of  $N/n$ ,  $N$  being the total number of containers in the lot and  $n$  the number of containers to be chosen (*see* Table 2). Every  $r$ th container thus counted shall be separated until the requisite number of containers is obtained from the lot to give samples for test.

**TABLE 2 NUMBER OF CONTAINERS TO BE CHOSEN FOR SAMPLING**

(Clauses F-2.2 and F-2.3)

LOT SIZE $N$	NO. OF CONTAINERS TO BE CHOSEN $n$
(1)	(2)
3 to 15	3
16 „ 40	4
41 „ 65	5
66 „ 110	7
Over 110	10

### **F-3. TEST SAMPLES AND REFEREE SAMPLES**

**F-3.1** Before drawing the test sample, thoroughly mix the contents of each container selected by shaking or by any other suitable means. Draw small portions of the material from different parts of each container selected (*see* Table 2). The total quantity of the material drawn from each container shall be sufficient to conduct the tests for all the characteristics given in Table 1 and shall not be less than 400 g.

**F-3.2** Mix thoroughly all portions of the material drawn from the same container. Out of these portions, a small but equal quantity shall be taken from each selected container and shall be well mixed together so as to form a composite sample of not less than 750 g. This composite sample shall be divided into three equal parts, one for the purchaser, another for the vendor and the third for the referee.

**F-3.3** The remaining portions of the material from each container (after a small quantity needed for formation of the composite sample has been taken out) shall be divided into three equal parts. These parts shall be immediately transferred to thoroughly dried sample receptacles which are then sealed air-tight, and labelled with all the particulars of sampling given under **F-1.8**. The material in each such sealed sample receptacle shall constitute a test sample. These individual samples shall be separated into three identical sets of test samples in such a way that each set has a sample representing each container selected (*see* Table 2). One of these three sets shall be marked for the purchaser, another for the vendor and the third for the referee.

**F-3.4** Referee samples shall consist of the composite sample (*see* **F-3.2**) and a set of individual test samples (*see* **F-3.3**) marked for this purpose and shall bear the seals of the purchaser and the vendor. These shall be kept at a place agreed to between the two.

#### **F-4. NUMBER OF TESTS**

**F-4.1** Tests for the determination of the sodium 3-acetylbenzyl-4-hydroxycoumarin content and Alice's ketone shall be conducted individually on each of the samples constituting a set of test samples (*see* **F-3.3**).

**F-4.2** Tests for the determination of the remaining characteristics, namely, sieving requirement and material insoluble in distilled water, shall be conducted on the composite sample as prepared under **F-3.2**.

#### **F-5. CRITERIA FOR CONFORMITY**

**F-5.1** A lot shall be declared as conforming to the specification if **F-5.1.1** and **F-5.1.2** are satisfied.

**F-5.1.1** The values of the test results on the composite sample for loss on drying and melting point shall satisfy the corresponding requirement given in Table 1.

**F-5.1.2** The values of the test results for the sodium salt of 3-acetylbenzyl-4-hydroxycoumarin content and Alice's ketone shall be recorded as shown in Table 3. The mean and range for the test results are calculated as below:

$$\text{Mean } (\bar{X}) = \frac{\text{Sum of the values of the test results}}{\text{Total number of test results}}$$

$$\text{Range } (R) = \text{Difference between the highest and lowest values obtained for the test results}$$

The appropriate expression as shown in col 6 of Table 3 shall be calculated. If the values of the expression satisfy the relevant condition as given in col 6 of Table 3, the lot shall be declared to have satisfied the requirement for the sodium salt of 3-acetonylbenzyl-4-hydroxycoumarin content and Alice's ketone.

TABLE 3 CRITERION FOR CONFORMITY

( Clause F-5.1.2 )

SL No.	CHARACTERISTIC	TEST RESULTS	MEAN	RANGE	CRITERION FOR CONFORMITY
(1)	(2)	(3)	(4)	(5)	(6)
i)	Sodium salt of 3-acetonylbenzyl-4-hydroxycoumarin, content	1, 2, 3.....n	$\bar{X}_1$	$R_1$	$(\bar{X} - 0.6 R) \geq 92$
ii)	Alice's ketone	1, 2, 3.....n	$\bar{X}_1$	$R_1$	$(\bar{X} + 0.6 R) \leq 750$

( Continued from page 2 )

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IS:	R <sub>s</sub>
560-1969 BHC, technical and refined ( <i>second revision</i> ) ...	4·50
563-1962 DDT, technical ( <i>revised</i> ) ...	4·50
634-1965 Ethylene dichloride carbon tetrachloride mixture ( 3 : 1 v/v ) ( <i>revised</i> )	4·50
882-1956 <i>gamma</i> -BHC ( lindane ) ...	2·00
1051-1957 Pyrethrum extracts ...	2·50
1052-1962 Dieldrin, technical ( <i>revised</i> ) ...	7·50
1055-1957 Nicotine sulphate solution ...	1·50
1251-1958 Zinc phosphide, technical ...	1·50
1306-1958 Aldrin, technical ...	3·00
1309-1958 Endrin, technical ...	2·00
1311-1966 Ethylene dibromide ( <i>first revision</i> ) ...	4·00
1312-1967 Methyl bromide ( <i>first revision</i> ) ...	5·50
1486-1969 Copper oxychloride, technical ( <i>first revision</i> ) ...	3·00
1488-1969 2, 4-D-Sodium, technical ( <i>first revision</i> ) ...	2·00
1682-1960 Cuprous oxide, technical ( fungicidal grade ) ...	2·50
1827-1961 Liquid amine salts of 2, 4-D ...	2·50
1832-1961 Malathion, technical ...	3·00
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